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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,762	12/28/2000	Kazuyuki Yanase	K0208.014	5214

23723 7590 05/29/2002

Patterson Belknap Webb & Tyler, LLP
Attention: I.P. Docketing
1133 Avenue of the Americas
New York, NY 10036

EXAMINER

SAYOC, EMMANUEL

ART UNIT	PAPER NUMBER
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3746

DATE MAILED: 05/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/720,762

Applicant(s)

YANASE ET AL.

Examiner

Emmanuel Sayoc

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshirou.

Due to the fact that the disclosure language of this reference is foreign to the examiner, the rejection is based solely on the figures. The claim language “for a pre-filled syringe into which liquid is charged” does not add any patentable structural limitation to the claimed invention.

With respect to claim 1, in Figure 1, Yoshirou discloses a syringe gasket wherein a peripheral side surface (3 or 4) of the gasket is in contact with an inner surface of the syringe barrel (not shown, but inherent). A restriction (1) is provided, and a periphery of a bottom surface of the gasket that is not in contact with the liquid is formed into a tapered shape (see edge adjacent to 4).

With respect to claim 4 and 5, the claims do not add any structural limitation on the claimed invention. Furthermore it was inherent, even trivial, in the art at the time the invention was made that any syringe device with a slid able plunger can be pre-filled with any liquid, including a contrast medium, and that the liquid can be tightly closed with the gasket by simply pre-applying pressure to the plunger.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshirou et. al. in view of Akaike et. al. It is possible that Yoshirou et. al. discloses the JIS hardness range of his gasket invention. In any case, Akaike et. al. in column 5 lines 58-59 discloses that a hardness of JIS of 20-85 is optimal for gaskets applied to syringe devices. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Yoshirou et. al. gasket by using a gasket material of 20-85 JIS hardness in order to achieve optimum gasket functionality within a syringe device.

5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshirou et. al. in view of Ito et. al. It is possible that Yoshirou et. al. discloses the material of the gasket. In any case, Ito in column 5 lines 1-7 discloses that a syringe gasket is commonly coated with a thermoplastic resin such as polyethylene or polypropylene (Teflon). Such material is optimum in that it eliminates the need for a lubricant and serves as a protective coating for the gasket. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Yoshirou et. al. gasket by using a gasket material of polyethylene or polypropylene, in order to achieve optimum gasket functionality and protection within a syringe device.

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Contact Information

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emmanuel Sayoc whose telephone number is (703)305-0054.

The examiner can normally be reached on M-F 8 A.M. - 6 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Thorpe can be reached on (703)308-0102. The fax phone numbers for the organization where this application or proceeding is assigned are (703)872-9302 for regular communications and (703)872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0861.

ECS

Emmanuel Sayoc
Patent Examiner
AU 3746

ECS
May 17, 2002


CHARLES G. FREAY
PRIMARY EXAMINER